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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ROSE, S

ART UNIT

PAPER NUMBER

1614

DATE MAILED:

01/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/48930

Applicant(s)

Examiner

S/487

R036

Group Art Unit

1614

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☐ Responsive to communication(s) filed on _____.
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1620 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1620 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claim(s) 1620 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 4 ☐ Interview Summary, PTO-413
- ☒ Notice of Reference(s) Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other _____

Office Action Summary

Applicant has presented twenty (20) claims, claims 1-10 drawn to the oral administration, and claims 11-20 drawn to "KITS" (no more than label information), of admittedly known species of acidic beverages having a pH of less than 5, which admittedly are considered to directly erode dental enamel, admittedly, according to Lussi et al. (1995), Caries Research Volume 29 pages 349-354; it being admitted prior art that the encompassed species of acidic low pH dental eroding beverages include: carbonated cola and other soft drinks; as well as non-carbonated citrus and other fruit juices; as well as tea; milk and milk based beverages; (containing fluoride and calcium, respectively), it being admitted prior art that fluoride and/or calcium can expectedly lessen dental erosion, the improvement to such dental eroding ingestible acid low pH beverages being that the beverage contains sodium or potassium phosphates or polyphosphate salts.

Only claims 6 and 16 recite and require that the beverage be "substantially free" of "one or more" of calcium or fluoride, (both admittedly found in encompassed species of low pH acidic milk and tea beverages).

The novelty of kit claims 11-20, over inadvertently overlooked not admitted prior art acidic beverages containing the sodium or potassium species of encompassed phosphates or polyphosphates (included described or taught for reasons other

than to treat dental erosion) (cited as known on the PTO-892 attached), (clearly meeting Part (a) of claim 1), is found in Part (b) of the "KIT", "INFORMATION THAT THE USE OF THE BEVERAGE COMPOSITION PROVIDING TREATMENT AGAINST DENTAL EROSION". The CCPA in 1947 in In re Haller, 73 USPQ 403, held that novelty cannot be predicated on printed instructions (or on a label to reconstitute or to dilute a known composition with water to use it as an insecticidal spray). This Court case never overturned is binding as a precedent herein since CCPA precedents are Federal Circuit precedents and Federal Circuit precedents are binding on USPTO examiners.

No claim recites the enabled percentages of the phosphate or polyphosphate. Claims 3-10, and 13-20 further recite a sweetener, not necessarily but encompassing sucrose (admittedly causing dental erosion), as well as non-nutritive sweeteners which do not.

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims fail to recite the enabled concentrations or percentages of the enabled phosphates or polyphosphate sodium or potassium salts providing treatment against dental erosion, in the absence of calcium and of fluoride salts known to provide effective treatment against dental erosion.

A review of the applicant cited admitted prior art cited on the PTO-1449 IDS includes:

Lussi et al. (1995) (as noted above) identifying the species of low pH tooth erosive acid beverages encompassed by these claims to include orange juice and other citrus and fruit juices, apple juice, Sprite, Coca cola, Lemon Lime and other carbonated soft drinks, Sweppes, sports drinks, wine and beer, to which fluoride has been added to minimize (but not totally prevent) tooth erosion.

Ruessner et al. (1975), describe and anticipate the addition, to encompass species of beverages, namely encompassed pH ranged canned and frozen orange juice, and carbonated lemon lime beverages, of encompassed percentages of phosphates, namely (page 366, column 1, Table I), 0.15% sodium hexametaphosphate (same as in applicant's Examples), 0.15% sodium trimetaphosphate; 0.21% monosodium orthophosphate (NaH_2PO_4); with or without 0.08% monofluorophosphate, or 0.15% calcium chloride, the levels of the phosphate compound selected to yield 0.5 mg of phosphorus per ml, and 0.5 mg per ml of calcium. A control group had no calcium or

phosphate supplement. Test groups of rats were fed citric acid containing beverages supplemented with .15% or .30% monocalcium phosphate.

Table 2 page 367 describes the effects of these encompassed species of phosphate and calcium supplemented low pH sugar sweetened beverages on tooth erosion in rats.

Ruessner et al. (1975) page 369, who concluded that the use of sodium phosphate salts as supplements in acid beverages did not produce significant decreases in molar erosion unless they contained fluoride, clearly meets these claims.

Gilmor (1969), on pages 194, 195, 199, 200, 203, 205 and 206 reports in the footnoted earlier work of:

Konig et al. Arch. Oral. Biol. Volume 3, pages 258-270 (June 1961) (footnote 31);

Muhlemann et al. Helv. Odont. Acta Volume 5 pages 4-9 (1961) (footnote 44);

each of whom administered encompassed species of phosphates in encompassed concentration to rats' drinking water an encompassed beverage, with and without fluoride as well, a feature not excluded by any claim presented, not even claims 6-16 which can include fluoride (if not with calcium).

Shibata et al. (1982), and McGaughey et al. (1977), (both cited by applicant) each motivates the inclusion in the diet of encompassed species of these condensed phosphates or

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polyphosphates in encompassed concentrations, with and without sucrose and/or glucose, as providing anti-carries activity, as tested at 2% phosphate level and high sugar diet in hamsters in the absence of fluoride, in Shibata et al.

Examiner cited Muhler (1970) South Africa 6904743, and McDonald et al. (1973), both cited on the PTO-892, anticipated the feature of adding encompassed species of phosphates to acid pH beverages to reduce tooth erosion, same as herein. The feature of selecting polyphosphate as phosphate sources would be "immediately envisioned" species under In re Schaumann et al., 197 USPQ 5.

Examiner cited U.S. patents cited on the PTO-892 each describe encompassed species of low pH acid beverages containing encompassed concentration of encompassed sodium or potassium phosphate salts, with no mention of their inherent property of thereby treating tooth erosion.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-20 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over each of: Muhler (1970) (as abstracted) and McDonald et al. (1973) (details as noted above), each anticipating the addition of such sodium or potassium phosphate salts to such a low pH acid beverage to reduce their tooth eroding potential. The selection of encompassed species of sodium or potassium polyphosphates or condensed phosphate salts as well as the selection of encompassed low pH acid beverage species, to practice this would be immediately envisioned, In re Schaumann et al., 197 USPQ 5. The feature of kit claims 11-20 of including information that the use of the beverage provides treatment against dental erosion is not patentable thereover, (In re Haller, 73 USPQ 403, CCPA-1947) since it is predicated on printed matter on the otherwise old beverage or its package.

Claims 1, 2, 11 and 12 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over applicant cited Gilmor (1969) citing Konig et al. (1961), and Muhlemann et al. (1961), (details as noted above), since "beverage" encompasses rats' drinking water to which encompassed species of condensed phosphates or polyphosphate salts were added, to observe the benefit against tooth erosion, as well as applicant cited Ruessner et al. (1975) (details as noted above) same rats' drinking water disclosure (same reasons). These claims do not exclude both fluoride and calcium both studied by these investigators for their protective benefit with encompassed condensed phosphates against tooth erosion in rats' drinking water (beverage).

Claims 1-20 are rejected under 35 U.S.C. § 103(a) as being unpatentable over McDonald et al. (1973) or Muhler (1970) (details as noted above), taken with any of the phosphate, condensed phosphate or polyphosphate salt supplemented low pH beverages of the U.S. patents cited on the PTO-892, namely, the commonly assigned Procter & Gamble patents to:

Calderas (sodium hexametaphosphate, same as herein), Smith et al., Montezinos (I-II), Ekanayake et al. (same), McKenna et al., Tung et al., Cirigliano et al. (I-II), Sokolik et al., and Zablocki et al. each describing encompassed species of beverages having a pH less than about 5, containing sodium

hexametaphosphate, (same as herein), or other encompassed species of sodium or potassium phosphate, condensed phosphate or polyphosphate salts, Calderas, for example employing 900 to 3000 parts per million polyphosphate with sodium hexametaphosphate, same as applicant herein in Examples 1-4), as the encompassed polyphosphate, in a non-carbonated beverage having a pH of between 2.5 and 4.5, as see column 4 lines 7-32 in fruit juices at column 7 lines 39-68, and tea at column 8 lines 12-28, with encompassed species of sweeteners at column 8 lines 30-68, also avoiding calcium as well as iron and magnesium fortification since these polyvalent cations combine to and inactivate the polyphosphate component of the non-carbonated beverages, as see column 9 lines 27-30.

Smith et al. (Procter & Gamble), similar to Calderas (Procter & Gamble), include 300 ppm to 3000 ppm of an encompassed polyphosphate having an average chain length of about 17 to about 60, an encompassed species of a non-carbonated beverage having a pH of between 2.5 and 4.5.

The prior art polyphosphate supplemented acid beverages could obviously be labeled with information to the effect that polyphosphates may prevent tooth caries, as see Shibata et al. (1982), that may reduce their tooth erosion potential of the acid low pH beverages, a property described by Lussi et al., (1995).

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Claims 1-20 are generic to a plurality of disclosed patentably distinct species comprising

One ultimate species each of:

- (a) A polyphosphate salt of the claim 1 formula;
- (b) a species of beverage encompassed by the claims: fruit juice, carbonated or non-carbonated beverage tea, milk, etc.;
- (c) (if further elected) a species of sweetener;
- (d) (if further elected) free of one or both of calcium and fluoride.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species, of each even though this requirement is traversed. If this application is filed under Rule 371, the legal authority is PCT Rule 13.2, Annex B, Part 1(f) "Markush Practice"; PCT Rule 13 and 35 U.S.C. § 372, rather than 35 U.S.C. § 121.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

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Election of species is required per MPEP § 803, 809.02(d) (Markush group claim practice, separate and burdensome fields of search required).

Patentably distinct Markush species are independent inventions, In re Webber, 198 USPQ 328, In re Haas, 198 USPQ 334. Divisional applications may be filed under 35 U.S.C. § 121, as a result of an Office requirement for an election of a patentably distinct species as made herein. In re Joyce, 115 USPQ 412, In re Herrick, 115 USPQ 412. This satisfies the "patentably distinct" criterion since the Examiner is not of the opinion that the various species are obviously unpatentable over one another, and each species (as noted above) is capable of independent manufacture, use, and sale, with the other components of the claimed formulations.

Applicant is further required to identify the claims that correspond to the elections as well as those that do not even if the requirements are traversed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shep Rose whose telephone number is (703) 308-4609. The examiner can normally be reached on Monday-Thursday from 7:30 A.M. to 6 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Cintins, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Shep Rose

Shep Rose
Senior Primary Examiner
Art Unit 1614

SKR:cdc
January 9, 2001

**SHEP K. ROSE
PRIMARY EXAMINER
GROUP 1200**